

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

*This document relates to:*

“Track Three Cases”

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MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS’ MEMORANDUM IN OPPOSITION TO PHARMACY  
DEFENDANTS’ MOTION TO EXCLUDE CARMEN CATIZONE**

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	BACKGROUND .....	1
III.	ARGUMENT.....	4
A.	Mr. Catizone’s Red Flag Analysis Is Reliable and Admissible. ....	5
B.	Mr. Catizone Has the Requisite Knowledge, Qualifications, and Experience to Testify that Defendants’ Systematic Failures to Resolve “Red Flags” Resulted in Filling Illegitimate Prescriptions on an Aggregate Basis. ....	11
C.	Mr. Catizone’s Opinions Regarding Opioid Diversion Are Admissible. ....	14
IV.	CONCLUSION .....	17

## TABLE OF AUTHORITIES

### Cases

<i>Allied Erecting &amp; Dismantling Co. v. U.S. Steel Corp.</i> , 2015 WL 1530648 (N.D. Ohio Apr. 6, 2015).....	14, 17
<i>Brown v. CVS Pharmacy, L.L.C.</i> , 982 F. Supp. 2d 793 (M.D. Tenn. 2013).....	6
<i>Cantrell v. GAF Corp.</i> , 999 F.2d 1007 (6th Cir. 1993) .....	16
<i>Clay v. Ford Motor Company</i> , 215 F.3d 663 (6th Cir. 2000) .....	10
<i>Gulf Med Pharmacy, Inc. v. Dhillon</i> , 469 F. Supp. 3d 1316 (M.D. Fla. 2020).....	7
<i>Heartland Pharmacy, Inc. v. Rosen</i> , 2021 WL 650350 (S.D. Fla. Feb. 18, 2021) .....	6, 12
<i>Heller v. D.C.</i> , 801 F.3d 264, (D.C. Cir. 2015).....	8
<i>Heller v. D.C.</i> , 952 F. Supp. 2d 133, (D.D.C. 2013).....	7
<i>In re Com. Fin. Servs., Inc.</i> , 350 B.R. 520, (Bankr. N.D. Okla. 2005) .....	8
<i>In re Nat’l Prescription Opiate Litig.</i> , 2020 WL 1526726 (N.D. Ohio Mar. 31, 2020) .....	14
<i>In re Nat’l Prescription Opiate Litig.</i> , 2019 WL 3934490 (N.D. Ohio Aug. 20, 2019).....	14
<i>In re Nat’l Prescription Opiate Litig.</i> , 2019 WL 3934597 (N.D. Ohio Aug. 20, 2019).....	14, 16, 17
<i>In re Nat’l Prescription Opiate Litig.</i> , 2019 WL 4178617 (N.D. Ohio Sept. 3, 2019).....	13, 17
<i>In re Nat’l Prescription Opiate Litig.</i> , 2019 WL 4254608 (N.D. Ohio Sept. 9, 2019).....	8

<i>In re Nat’l Prescription Opiate Litig.</i> , 477 F. Supp. 3d 613 (N.D. Ohio 2020).....	1, 3, 6
<i>Lovelace v. Pediatric Anesthesiologists, P.A.</i> , 2014 WL 8136184 (W.D. Tenn. Nov. 14, 2014).....	8
<i>Pharmacy Doctors Enterprises v. DEA</i> , 789 F. App’x 724 (11th Cir. 2019) .....	6
<i>Przybysz v. City of Toledo</i> , 302 F. Supp. 3d 915 (N.D. Ohio 2017), <i>aff’d</i> , 746 F. App’x 480 (6th Cir. 2018).....	16
<i>Redmond v. United States</i> , 194 F. Supp. 3d 606 (E.D. Mich. 2016).....	8
<i>Romero v. Hanisch</i> , 2010 WL 1812578 (D.S.D. May 3, 2010) .....	4
<i>Surles ex rel. Johnson v. Greyhound Lines, Inc.</i> , 474 F.3d 288 (6th Cir. 2007) .....	10
<i>Tennessee Bank Nat’l Ass’n v. Barreto</i> , 268 F.3d 319 (6th Cir. 2001)) .....	14
<i>United States v. Bek</i> , 493 F.3d 790 (7th Cir. 2007) .....	13
<i>United States v. Fabode</i> , 2021 WL 1560084 (E.D. Mich. Apr. 21, 2021).....	12
<i>United States v. Iriele</i> , 977 F.3d 1155 (11th Cir. 2020) .....	12
<i>United States v. Lang</i> , 717 Fed. App’x 523 (6th Cir. 2010). .....	16
<i>United States v. Otuonye</i> , 995 F.3d 1191 (10th Cir. 2021) .....	12
<i>United States v. Smith</i> , 573 F.3d 639 (8th Cir. 2009) .....	3
<b>Rules</b>	
Fed. R. Evid. § 702 .....	10
21 CFR § 1306 .....	3, 11

## **I. INTRODUCTION**

Carmen Catizone is among the leading experts in America on pharmacy practice. Through his long career, he has obtained unmatched professional experience and expertise on issues relating to “red flags” of prescription opioid diversion, and the consequences of ignoring red flags. He has provided expert opinions on similar topics multiple times, including in cases for the Department of Justice and in testimony to the United States Senate. His opinions are important to the upcoming trial, as they pertain to the kind of “red flag” analysis anticipated by prior orders of the Court. *See, e.g., In re Nat’l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020) (explaining that red flags “include indicia that would be very difficult, if not impossible, for a human pharmacist to identify consistently absent a system to aggregate, analyze, and provide feedback to the pharmacist about the prescription. In other words, some prescriptions are not suspicious on their face but raise bright red flags when compared with other prescriptions in a database.”).

Defendants’ *Daubert* motion mainly consists of mischaracterizing a few snippets of Mr. Catizone’s testimony from a 527-page deposition transcript and re-litigating arguments essentially identical to what the Court rejected in pre-trial rulings from CT1. Nothing in Defendants’ motion casts doubt on the reliability and admissibility of Mr. Catizone’s opinions, which will assist the jury in understanding what kinds of “red flags” associated with opioid prescriptions Pharmacy Defendants need to be on the alert for, why they have duties to investigate and resolve these “red flags,” and how their systematic failures in this regard helped fuel the opioid crisis in Lake and Trumbull Counties. Pharmacy Defendants’ motion should be denied.

## **II. BACKGROUND**

Mr. Catizone is one of the foremost authorities on the practice and regulation of pharmacies. He holds two degrees in the field of pharmacy, and has practiced as a registered

pharmacist for decades.<sup>1</sup> From 1988 to 2020, Mr. Catizone served as the Executive Director and the CEO of the National Association of Boards of Pharmacy (“NABP”), which is an impartial organization consisting of state agencies that regulate the practice of pharmacy. Expert Report of Carmen A. Catizone, May 19, 2021, at 4 (“Report”).<sup>2</sup> NABP works with state boards of pharmacy to develop, implement, and enforce uniform standards of pharmacy practice to protect public health and safety. *Id.* NABP has also focused on understanding the impact of pharmacy practice on the opioid epidemic, and developed a consensus set of “red flag” warning signs for pharmacists to apply in dispensing opioids. *Id.* at 34, n.50. Mr. Catizone has been at the helm of all these activities since at least 1988. He has also taught DEA agents at Quantico about drug diversion, and served as a liaison to both the DEA and the Food and Drug Administration, chairman of the Pharmacy Technician Certification Council, president of the National Conference of Pharmaceutical Organizations, and member of the Board of Trustees of the United States Pharmacopeia. He has received honors and awards from prestigious universities, federal agencies and governmental bodies, and even a “Pharmacist of the Year” award from a leading industry publication. *See Report* at 4–5.

In the upcoming trial, Mr. Catizone’s testimony will focus on a topic that has been central to the litigation through two years of discovery and motion practice, *i.e.*, the fact that there is ***“no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances.”*** *In re Nat’l*

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<sup>1</sup> Defendants trivialize Mr. Catizone’s experience by stating he practiced full-time as a pharmacist for only “two years.” *See Mot.* at 2. But Mr. Catizone testified at his deposition that he worked as a pharmacist part-time while also working at NABP, much longer than two years. *See Catizone Dep.* at 87:3–87:7. Mr. Catizone’s deposition transcripts are filed on the docket at ECF No. 3859.

<sup>2</sup> Defendants submitted excerpts of Mr. Catizone’s Expert Report as “Exhibit B” to their *Daubert* motion. Plaintiffs have filed the entire Report to the Court’s docket. *See ECF No. 3852.*

*Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020) (emphasis added). Mr. Catizone will offer expert testimony on topics encompassed by the Court’s prior ruling, including: what are the contours of the “obligations” that the Court mentioned in its prior rulings? what are the “red flags of possible diversion”? and how must the Pharmacy Defendants “conclusively resolve” the red flags prior to dispensing the prescriptions?

In addition, Mr. Catizone has reached case-specific conclusions about the Pharmacy Defendants’ opioid compliance practices based his review of the dispensing data they produced in discovery. From this data, Mr. Catizone was able to catalog how many opioid prescriptions Defendants dispensed to customers in Lake and Trumbull Counties that exhibited “red flags” that were not resolved prior to dispensing. Based on his decades of experience dealing with opioid diversion from the perspective of a regulator, he was also able to form opinions about the consequences of Defendants’ conduct on public health, consistent with this Court’s prior *Daubert* rulings about aggregate proof.

Mr. Catizone’s qualifications to provide reliable expert testimony on these topics is well documented. He has been accepted as a testifying expert in at least six federal trials (including in the Northern District of Ohio) and numerous DEA enforcement actions. Report at 5–6 (listing appearances). No court has excluded his testimony. *See* Catizone Dep. 130:3–130:8. And some federal judges have praised his knowledge of pharmacy practice, including his knowledge of the “corresponding responsibility” of pharmacists under 21 C.F.R. 1306.04(a).<sup>3</sup>

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<sup>3</sup> *See Romero v. Hanisch*, No. CIV.08-5040-JLV, 2010 WL 1812578, at \*6 (D.S.D. May 3, 2010) (noting Mr. Catizone’s “impressive credentials”); *see also United States v. Smith*, 573 F.3d 639, 654 (8th Cir. 2009) (noting that Mr. Catizone’s job required “a working knowledge of what constitutes a valid prescription”).

Mr. Catizone has also provided expert testimony to the United States Congress, as well as state legislatures and state or federal agencies.<sup>4</sup> His acceptance by the United States Senate and federal courts alike on issues relating to opioid diversion bears directly on his ability to provide reliable testimony on similar issues here, including the risks and harms associated with Defendants’ systematic violations of their anti-diversion duties. *See* Report at 3–4.

### III. ARGUMENT

Defendants’ main argument against the admissibility of Mr. Catizone’s red flag analysis is that a single criterion incorporated into his report—*i.e.*, his opinion that traveling more than 25 miles to fill an opioid prescription constitutes a “red flag” of opioid diversion—is allegedly subject to fair-minded disagreement by different pharmacists. Defendants quibble with the 25-mile opinion as allegedly being both too “arbitrary” and too “mechanistic,” which they claim leads to “incorrectly flagged” prescriptions. Mot. at 3–4. None of these criticisms are well explained, however. At bottom, Defendants seem to just disagree the “distance traveled” red flag can be reduced to an actual distance in miles—even though courts and the DEA have both found that it can be. [REDACTED]

[REDACTED]

[REDACTED]

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<sup>4</sup> *See, e.g.*, Dec. 12, 2017 Statement of C. Catizone Before the Senate Committee on the Judiciary at 5, *available at* <https://www.judiciary.senate.gov/imo/media/doc/12-12-17%20Catizone%20Testimony.pdf>; *see also* July 14, 2004 Testimony Before the Senate Committee on the Judiciary, *available at* <https://www.govinfo.gov/content/pkg/CHRG-108shrg43983/html/CHRG-108shrg43983.htm> (providing expert testimony concerning the implications of the illegal importation of drugs from the perspective of public health and patient safety); July 16, 2013 Testimony Before House Energy and Commerce Subcommittee on Health, *available at* <https://docs.house.gov/meetings/IF/IF14/20130716/101137/HHRG-113-IF14-Wstate-CatizoneC-20130716-U1.pdf> (providing expert testimony regarding pending legislative proposals and regulatory framework relating public-health risks of pharmacy compounding and manufacturing).



Defendants also contend that Mr. Catizone should be precluded from opining that any particular red flag prescription was medically unnecessary and/or diverted. On the present record, Mr. Catizone does not intend to offer any such opinion about any specific prescriptions. He will, however, testify that prescriptions dispensed with unresolved red flags are not valid prescriptions. Given the sheer volume of invalid prescriptions sold by Defendants in Ohio, Mr. Catizone opines that the Defendants failed to guard against opioid diversion, which resulted in aggregate public harm. *See, e.g.*, Report at 104–105. Defendants assert this is too speculative, but they are wrong. Mr. Catizone’s whole career has been concerned with how pharmacy practice impacts public health. He testifies that the high risk of opioid diversion is the very reason pharmacists have red flag obligations to begin with; when they breach those obligations, the risks materialize.

**A. Mr. Catizone's Red Flag Analysis Is Reliable and Admissible.<sup>5</sup>**

<sup>5</sup> The legal standards applicable to *Daubert* motions are set forth in *Plaintiffs' Opposition to Certain Defendants' Daubert Motion to Exclude the Opinions Offered by James Rafalski*, to which the Court is respectfully referred.

Pharmacy Defendants may not fill opioid prescriptions exhibiting “red flags” unless they “conclusively resolve red flags of possible diversion prior to dispensing those substances.” *In re Nat’l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020). All of the “red flags” Mr. Catizone identified in his report—such as doctor shopping, combinations of commonly abused drugs, paying by cash, traveling long distances to the pharmacy, and so forth—are widely recognized by courts, the DEA, state boards of pharmacy, industry associations, and even Pharmacy Defendants themselves. *See* Report at 30–31 (discussing Defendants’ compliance policies that discuss “red flags”); *see also Heartland Pharmacy, Inc. v. Rosen*, 21-14037-CV, 2021 WL 650350, at \*4 (S.D. Fla. Feb. 18, 2021) (noting that the DEA interprets “corresponding responsibility” to require “pharmacist to recognize and resolve red flags on the prescriptions prior to filling them” and discussing red flags); *Pharmacy Doctors Enterprises v. DEA*, 789 F. App’x 724, 730 (11th Cir. 2019) (noting that “red flags” are “indicia that the prescription was not issued for a legitimate medical purpose and would likely be diverted to non-medical uses,” and that “the absence of any documentation of resolution of red flag is probative of a failure to resolve it”); *Brown v. CVS Pharmacy, L.L.C.*, 982 F. Supp. 2d 793, 803 (M.D. Tenn. 2013) (discussing “red flags” under both Sixth Circuit precedent and Tennessee law). Mr. Catizone’s core opinions about “red flags” are consistent with mainstream thinking about the most common indicia of opioid diversion and “which indicate[] to the pharmacist that further diligence is needed on that prescription because there could be diversion or abuse or a problem.” Catizone Dep. 212:23–212:25.<sup>6</sup> Defendants nevertheless seek to exclude these red-flag opinions, making two overlapping arguments.

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<sup>6</sup> Defendants intend to offer their own expert testimony on topics relating to “red flags,” their use in the practice of pharmacy and pain management, and pharmacists’ “corresponding responsibility.”

**First**, Defendants assert that Mr. Catizone’s red flag criteria are “arbitrary.” Mot. at 3. This argument ostensibly applies to each of the “red flags” he identified in his report, even though Defendants discuss only *one* of them in their *Daubert* motion, *i.e.*, that traveling more than 25 miles to a pharmacy to fill an opioid prescription is a red flag.

During his deposition, Mr. Catizone stated that his 25-mile metric “is a parameter that, as I’ve determined, is a safe parameter to utilize.” Catizone Dep. 399:9–13. This conclusion is supported by both his professional experience, and reliable external sources. *Id.* 207:4–208:12 (discussing “three primary sources of information he relied upon besides experience”). Mr. Catizone also explained in his report that “[t]he use of 25 miles as a reference point is based upon standards used by states in establishing and permitting telepharmacies,” which serve remote rural communities. Report at 32–33.

Moreover, courts and the DEA have also embraced the 25-mile metric. *See, e.g., Gulf Med Pharmacy, Inc. v. Dhillon*, 469 F. Supp. 3d 1316, 1317, 2020 WL 3428034 (M.D. Fla. 2020) (finding that traveling approximately 45 miles *round trip* is a red flag and rejecting the pharmacy’s argument that “it has no way of knowing how far, in DEA’s opinion, is too far for a patient to travel”). Thus, Mr. Catizone’s opinion about 25 miles is *not* arbitrary, but is clearly connected to his professional judgment and the existing facts. *See Heller v. D.C.*, 952 F. Supp. 2d 133, 142 (D.D.C. 2013) (permitting experts to testify based on existing facts and “each expert’s professional judgment obtained through long experience in the field” about how gun-control policy impacts behavior of gun owners), *affirmed by Heller v. D.C.*, 801 F.3d 264, 272 (D.C. Cir. 2015) (noting that experts relied on professional judgment and experience, and although they provided minimal explanation about “the connection between their experience and their conclusions,” such issues

“go to the weight of the testimony, not its admissibility.”); *In re Com. Fin. Servs., Inc.*, 350 B.R. 520, 534 (Bankr. N.D. Okla. 2005) (finding that expert’s choice of methodology “constitutes the exercise of professional judgment, which may be evaluated at trial in assessing the weight to accord the testimony based thereon.”). Mr. Catizone’s opinion “refers to outside, neutral, authoritative sources showing the bases for his methodology,” *In re Nat’l Prescription Opiate Litig.*, 2019 WL 4254608, at \*7 (N.D. Ohio Sept. 9, 2019), and is based on his specialized experience in pharmacy practice and regulation for thirty years. That makes it admissible. The same is true for all of Mr. Catizone’s opinions about red flags.

Finally, it is irrelevant that a different hypothetical pharmacist might feel that “30 miles or 20 miles” is a better yardstick for the red flag. Mot. at 3. Disagreement between experts about a particular standard of care is commonplace and does not render testimony “arbitrary” or inadmissible. *See Redmond v. United States*, 194 F. Supp. 3d 606, 618 (E.D. Mich. 2016) (denying motion to exclude expert testimony and finding that “the fact that the government’s expert and the plaintiff’s disagree as to the particulars of the standard of care . . . does not establish that the testimony of either witness is unsuitable for presentation at trial”); *Lovelace v. Pediatric Anesthesiologists, P.A.*, 2014 WL 8136184, at \*2 (W.D. Tenn. Nov. 14, 2014) (finding that if a party “disagree[s] with the testimony regarding the proper standard of care or the facts of the case relied upon, the appropriate course of action is to rebut this testimony with other witnesses or undermine its credibility on cross-examination, not to exclude it from the jury.”); *see also In re Nat’l Prescription Opiate Litig.*, 2019 WL 4254608, at \*8 (N.D. Ohio Sept. 9, 2019) (denying motion to exclude expert testimony and stating that if “experts disagree,” opposing counsel “will have the opportunity to identify and develop these matters through cross examination and the proffer of their own experts”).

**Second**, Defendants contend Mr. Catizone admits his methodology “incorrectly flags some prescriptions as having red flags,” which they claim is fatal to his opinions. Mot. at 3. This is a disingenuous argument because it hinges on semantics. Specifically, Defendants suggest that in the scenario where an opioid prescription exhibits a “red flag”—and the pharmacist performs sufficient due diligence to *resolve* the red flag—the prescription was “incorrectly flagged” and should be regarded as an “erroneously identified” red flag. Based on this flawed logic and wordplay, Defendants contend there is a potentially significant error rate associated with Mr. Catizone’s purportedly “erroneous” red flag prescriptions.

Of course, there is no evidence even a single red flag is erroneous. A red flag is simply a warning sign for the risk of opioid diversion. That a suspicious prescription sometimes has an innocuous explanation does not mean it was *not* suspicious; and a red flag is not rendered “erroneous” merely because it is resolved by due diligence. No DEA case or court decision embraces this kind of backward logic.

The snippet of Mr. Catizone’s deposition testimony Defendants rely on for this proposition is taken out of context. Mr. Catizone agrees, of course, that some customers may possess a valid reason to travel over 25 miles to fill an opioid prescription. In this context, he answered “yes” to a convoluted and leading question (to which there was an objection) about whether that means “they are not really red flags.” Catizone Dep. 218:5. Based on the context of his deposition and expert report, however, it is crystal clear Mr. Catizone’s does not agree that opioid prescriptions he identified in his report were “erroneously” flagged.<sup>7</sup>

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<sup>7</sup> Furthermore, Mr. Catizone testified that he saw no documentary evidence that Defendants resolved *any* of the red flags on the prescriptions he identified. Catizone Dep. 218:7-13. Thus, even accepting Defendants’ self-serving argument, there were no “incorrectly flagged” opioid prescriptions, and thus no error rate for his analysis.

And regardless, Mr. Catizone's opinions would be admissible even if he failed to test for an error rate. *Clay v. Ford Motor Company*, 215 F.3d 663, 668 (6th Cir. 2000) (an expert's failure to test goes to weight not admissibility). An expert relying on his experience need only adequately "explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. § 702, advisory committee note, 2000 amendment; *Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 296 (6th Cir. 2007) (finding that expert's "threat assessment experience" qualified him to testify where he "detail[ed] his threat assessment experience," "list[ed] the materials he reviewed in formulating his opinion," and "expressly state[d] that his opinions were based on his extensive experience and review of relevant materials"); *Heller v. D.C.*, 952 F. Supp. 2d at 142. Mr. Catizone has met that standard. Catizone Dep. 86:9–89:4 (stating that his opinions "are based on [his] experience and expertise in the practice and regulation of pharmacy" going back to 1988); 153:13–153:17 (explaining that he relied on his experience and all the years of work in this industry and knowledge he has gained as part of his opinions). In addition to his experience, Mr. Catizone also relied on several supporting sources, including "DEA guidance, guidance from State Boards of Pharmacy, negotiated consensus documents published by the National Association of the Boards of Pharmacy, and by industry trade groups such as the National Association of Chain Pharmacies." Report at 28–29.

In sum, contrary to Defendants' main argument in their *Daubert* motion, Mr. Catizone has repeatedly and adequately explained how his conclusions flow from his experience and the record evidence. His opinions are therefore relevant, reliable, and helpful to the jury, and should not be excluded.

**B. Mr. Catizone Has the Requisite Knowledge, Qualifications, and Experience to Testify that Defendants’ Systematic Failures to Resolve “Red Flags” Resulted in Filling Illegitimate Prescriptions on an Aggregate Basis.**

In Section II of Defendants’ motion they contend Mr. Catizone’s testimony should be limited to “opining about prescriptions *potentially* subject to red flags,” and he “should not be permitted to suggest that these prescriptions were (or were likely to have been) written for an illegitimate medical purpose.” Mot. at 5. There is no basis for this limitation. Defendants’ entire argument is only four sentences and does not cite any legal authority.<sup>8</sup>

To be clear, however, Mr. Catizone does not intend to testify about specific, individual prescriptions that were not written for a legitimate medical purpose. He has stated that his opinions relate to Defendants’ systematic dispensing of opioid prescriptions without clearing “red flags” (owing to a failure of their anti-diversion policies), which in the aggregate led to an increase in prescriptions that are not valid prescriptions under 21 C.F.R. § 1306.04(a) (which is the CSA provision that embodies the pharmacists’ “corresponding responsibility” and states that “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice” and that “a corresponding responsibility rests with the pharmacist who fills the prescription” to ensure it is an effective prescription).

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<sup>8</sup> As an initial matter, Defendants do not explain what they mean by “prescriptions *potentially* subject to red flags.” Mot. at 5. An opioid prescription either exhibits a red flag, or it does not. Report at 27–28 (“A pharmacist’s corresponding responsibility and determination of whether a prescription issued for a controlled substance is valid and legitimate, requires systems and actions to recognize, investigate, and resolve signs of a prescription’s invalidity (red flags) ‘arising during the presentation of a prescription which creates a reasonable suspicion that the prescription is not, on its face, legitimate.’”). There is no such thing under Mr. Catizone’s analysis as a prescription “*potentially* subject to red flags.” Red flags create a presumption of illegitimacy; unless that presumption is resolved based on documented due diligence, the red flag exists. See Catizone Dep 158:19–163:15.

This kind of expert testimony is regularly permitted in cases involving allegations that pharmacies dispensed “red flag” opioid prescriptions. *See, e.g., United States v. Iriele*, 977 F.3d 1155, 1170 (11th Cir. 2020) (noting that an expert witness reasonably concluded that pharmacy filled opioid prescriptions that were not medically necessary based on indicia of “red flags” such as suspicious combinations of prescription products); *United States v. Otuonye*, 995 F.3d 1191, 1211 (10th Cir. 2021) (noting that “red flags” include quantities or combinations of drugs prescribed, cash payments, and distance travelled, and that expert testimony demonstrated that “‘red flags’ should have alerted [the pharmacist] that the prescriptions were illegitimate.”); *Heartland Pharmacy, Inc. v. Rosen*, 21-14037-CV, 2021 WL 650350, at \*4–5 (S.D. Fla. Feb. 18, 2021) (finding that DEA demonstrated pharmacy’s failure to resolve red flags would likely result in opioid abuse, and rejecting the pharmacy’s contention that “failure to resolve red flags” on a prescription is not the same as “proof that the prescription is illegitimate”). These cases directly refute Defendants’ argument because they establish that experts can reliably deduce from aggregate dispensing data—much like the data that Mr. Catizone analyzed here—valid opinions that pharmacists were dispensing medically unnecessary opioid prescriptions in violations of their anti-diversion obligations under 21 C.F.R. § 1306.04(a). Indeed, Mr. Catizone himself has applied this kind of methodology to opine on whether a pharmacist’s opioid dispensing was outside the course of professional pharmacy practice based on review of dispensing records—without analyzing the medical necessity of each prescription. *See, e.g., United States v. Fabode*, 2021 WL 1560084, at \*3 (E.D. Mich. Apr. 21, 2021). *See also United States v. Bek*, 493 F.3d 790, 797–99 (7th Cir. 2007) (acknowledging another expert’s conclusion, based analysis of certain dispensing data, that defendant had “general practice of prescribing controlled substances outside the course of professional conduct”).



Equally important are this Court's own previous rulings that Plaintiffs are entitled to present their case through aggregate evidence, including through expert testimony. Defendants' arguments against Mr. Catizone's "causation" opinions are mostly a rehash of arguments the Court already rejected. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 4178617, at \*3 (N.D. Ohio Sept. 3, 2019) (denying summary judgment because "the Court finds Plaintiffs' aggregate proof of causation sufficient to overcome summary judgment" and that "given the massive increases in the supply of prescription opioid . . . combined with evidence that suggests there was a complete failure by Defendants to maintain effective controls against diversion, a factfinder could reasonably infer that these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs"). Similarly, when the Court denied Pharmacy Defendants' attempt to implead "Jane and John Doe prescribers," the Court explained that the CT3 trial:

will focus on Pharmacies' policies and procedures, through analysis of aggregate dispensing data showing the entirety of the information the Pharmacies had when dispensing opioids. After hearing this evidence, the jury will be tasked with deciding whether the Pharmacies engaged in intentional or unlawful conduct. Thus, a finding of Defendants' liability will be based on the distinct duties of the Pharmacies, involving facts largely independent of any individual Prescriber or prescription."

*In re Nat'l Prescription Opiate Litig.*, 2020 WL 1526726, at \*2 (N.D. Ohio Mar. 31, 2020).

The Court has applied the same kind of analysis in deciding various *Daubert* issues. For example, when Defendants moved to exclude opinions of Plaintiffs' expert, former DEA diversion investigator James Rafalski, they argued his methodology was unreliable because "Rafalski has not tested the results to determine if, in fact, they flagged orders that were actually suspicious." *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934490, at \*5–6 (N.D. Ohio Aug. 20, 2019). The Court disagreed and explained that Mr. Rafalski's "extensive field experience" permitted him to reliably opine on "methodologies available to flag potentially suspicious orders" without the

need to test the results of such methods. The Court reasoned that the relevant reliability concerns should focus instead on personal knowledge or experience, a standard that Mr. Rafalski met. *Id.* (citing *First Tennessee Bank Nat'l Ass'n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001)); *see also In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at \*10 (N.D. Ohio Aug. 20, 2019) (admitting expert testimony on causation in the aggregate, and rejecting Defendants' criticisms that expert should have addressed the actions of individual manufacturers instead of analyzing marketing conduct in the aggregate).

The same analysis should apply here. Mr. Catizone's highly-specialized experience, combined with his extensive personal knowledge in this field, provides the requisite foundation for his expert opinions. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934490, at \*6; *First Tennessee Bank*, 268 F.3d at 335; *Allied Erecting & Dismantling Co. v. U.S. Steel Corp.*, 2015 WL 1530648, at \*1 (N.D. Ohio Apr. 6, 2015). It is immaterial that Mr. Catizone did not endeavor to granularly identify each diverted opioid pill, as it would be effectively impossible to do so in a lawsuit of this magnitude. It is sufficient for Mr. Catizone to make conclusions about the consequences of the sheer magnitude of "red flag" prescriptions *overall*. Just as the Court ruled previously: "Defendants are free to *demonstrate at trial* that, under the circumstances, the orders were not suspicious, they performed adequate due diligence, and/or it was otherwise reasonable for them to ship subsequent orders." 2019 WL 3934490, at \*7 (emphasis added).

**C. Mr. Catizone's Opinions Regarding Opioid Diversion Are Admissible.**

Defendants' final argument is effectively that Mr. Catizone's experience working with boards of pharmacy and legislatures across the country for 30-plus years to protect public health does not equip him to provide reliable testimony about the likely public health consequences of Defendants' disregard of controlled substances laws. Defendants are wrong. Governing bodies

across America have relied on Mr. Catizone's authoritative expertise on these issues, and it would be appropriate for the jury in this case to hear his opinions too. Mr. Catizone is among a discrete set of experts qualified to discuss the likely public health consequences of systematic breakdowns in pharmacy standards of care.

First, Defendants' argument is largely predicated on mischaracterizing Mr. Catizone's testimony. They claim he "admitted that his methodology fails to identify prescriptions that were actually diverted." Mot. at 5–7. That is not true. He merely agreed that his expert report did not endeavor to analyze which specific prescriptions were diverted. Catizone Dep. 167:8–167:11.<sup>9</sup> This is consistent with the Court's recognition Plaintiffs may present their case through aggregate analysis and aggregate proof, and Defendants can attack Plaintiffs' evidence as they wish.

Second, an expert's opinion on causation is admissible even where an expert may not account for certain reasons of causation. *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at \*10 (N.D. Ohio Aug. 20, 2019) (explaining that Defendants can cross-examine the expert at trial regarding alleged causes for increases in opioid prescriptions and whether her opinions are unsound). The *Daubert* standard is liberal, and does not require expert opinions to be bulletproof. *United States v. Lang*, 717 Fed. App'x 523, 534 (6th Cir. 2010). Here, Defendants argue that, "Mr. Catizone offers no basis for his assumption that the number of drug overdoses correlates directly with diversion of prescription opioid medication," and they claim that nothing "qualifies him to testify about any link between the number of overdoses (or overall number of dispensed opioids) and the number of diverted opioid prescriptions." Mot. at 6. But as noted previously, Defendants'

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<sup>9</sup> Defendants also misrepresent that Mr. Catizone was unfamiliar with a SAMHSA "study" about the frequency of medicine cabinet diversion. Mot. at 5–6. Mr. Catizone actually testified he was familiar with the exact same data Defendants mentioned—he just didn't regard the "data" as a "study." See Catizone Dep. 171:22–174:1.

criticisms go to the *weight* of Mr. Catizone's testimony, not admissibility. Defendants may perceive that Mr. Catizone's methods contain "imperfections in [his] analysis, but they do not, either individually or in the aggregate, render [them] unreliable." *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at \*10 (N.D. Ohio Aug. 20, 2019).

Indeed, courts permit expert testimony regarding causation where the expert's conclusion is premised on recognized sources of harm that, according to the expert's experience, increase the likelihood of materializing into damage. *See Cantrell v. GAF Corp.*, 999 F.2d 1007, 1014 (6th Cir. 1993) (finding no error in expert testimony about the likely "consequences of exposure to certain conditions" in an asbestos exposure case even though the expert acknowledged that "the incidence of laryngeal cancer in the plant does not alone prove that asbestos was the culprit."); *see also Przybysz v. City of Toledo*, 302 F. Supp. 3d 915, 926 (N.D. Ohio 2017), *aff'd*, 746 F. App'x 480 (6th Cir. 2018) (finding former DEA expert testimony admissible because expert "is qualified, his testimony is record-supported, and he explained how his experience led" to his opinion).

Here, Mr. Catizone's specialized experience in this field provides the requisite foundation for his opinions. The heart of his work at NABP included identifying when opioid dispensing or distribution practices were likely to harm the public. And Mr. Catizone has explained, both in his report and deposition, how his experience and review leads logically to his opinions regarding diversion. *See, e.g.*, Report at 4, 104; Catizone Dep. 522:15–525:17; 174:3–176:25. *See also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 F.R. 62316-01 (finding expert's "knowledge and experience, rather than the specific *Daubert* factors, provide the appropriate analytical framework for evaluating the reliability of his opinion"). On this foundation, Mr. Catizone can opine that Defendants' dispensing practices were imprudent, and in the aggregate, resulted in more opioids being dispensed than should have been dispensed under

the circumstances. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 4178617, at \*2 (causation can be established with “evidence that shows [plaintiffs] have suffered the sort of injury that would be an expected consequence of the alleged wrongful conduct”).

Ultimately, Defendants’ arguments against Mr. Catizone’s opinions go to the *weight of the evidence*, not exclusion. *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at \*9 (N.D. Ohio Aug. 20, 2019) (the “validity of the [expert’s method] goes to the weight the trier of fact will accord this analysis, not its admissibility”); *Allied Erecting & Dismantling Co. v. U.S. Steel Corp.*, 2015 WL 1530648, at \*9 (N.D. Ohio Apr. 6, 2015) (admitting expert testimony, and noting that “[a] court should not use its gatekeeping function to impinge on the role of the jury or opposing counsel”). Defendants’ reasons for excluding his opinions are without merit. Mr. Catizone should be permitted to offer opinions that Pharmacy Defendants’ sales of invalid prescription on a massive scale led to opioid diversion.

#### IV. CONCLUSION

For the foregoing reasons, the Court should deny Defendants’ motion to exclude or limit the opinions of Carmen Catizone.

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 23<sup>rd</sup> day of December 2021, I have electronically filed the foregoing with the Clerk of Court using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court's CM/ECF System.

/s/ Anthony D. Irpino  
Anthony D. Irpino